

## Biomedical Equipment That Is Y2K Compliant Electronic File (E-File) Reporting Format Instructions

<u>Column</u>	<u>Column Name</u>	<u>Column Width</u>	<u>Column Description</u>
A	Man-name	80	Name of the Manufacturer submitting the product information.
B	Division	50	Name of the Division, if this report is for ONE specific division. Complete ONE electronic file for each division that manufacturers biomedical equipment. Please leave blank if you are reporting for the entire company.
C	Operator-nbr	7	If the Manufacturer submitting Y2K compliant product information is FDA regulated, please enter your FDA-assigned Owner/Operator Number, which is a 7-digit number.
D	Class-name	80	FDA Classification Number ( <i>see the enclosed list of product classification names</i> ) <ul style="list-style-type: none"> <li>• CFR Number – 8xx.xxxx OR</li> <li>• Generic Description – for products that have not been classified by the FDA or is scientific research equipment (e.g., mass spectrometer)</li> </ul>
E	Prod-name	255	Commonly used name that identifies the product (i.e., the name that appears on the product label).
F	Model-nbr	100	Model number or range of numbers associated with the product that uniquely identifies it.
G	Original-manufacturer	80	Identify the name under which this product was originally marketed, if it is different than Column A.
H	Serial-nbr	100	Serial number or range of numbers for the compliant product, if applicable. Use "All" to indicate all serial numbers associated with the compliant product.
I	SW-version	100	Software version or range of numbers for the compliant product, if applicable. Use "All" to indicate all software version numbers associated with the compliant product.
J	FirstName	50	First Name of the Y2K Contact for the manufacturer.
K	LastName	50	Last Name of the Y2K Contact.
L	Address1	50	Street address #1 of the Y2K Contact.
M	Address2	50	Street address #2 of the Y2K Contact.
N	City	50	City of the Y2K Contact.
O	State	50	State/Province of the Y2K Contact.
P	Postal	50	Postal Code of the Y2K Contact.
Q	Country	50	Country of the Y2K Contact.
R	Telephone	50	Telephone number of the Y2K Contact.
S	Fax	50	Fax number of the Y2K Contact.
T	Email	50	E-Mail address of the Y2K Contact.
U	SubType	1	Type of Submission – Select only one for each row item. <ul style="list-style-type: none"> <li>• A – Add/New (default)</li> <li>• C – Change/Update</li> <li>• D – Deletion</li> </ul>